

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Study of effectiveness and non effectiveness of abdominal massage and non-nutritive sucking on clinical outcomes in preterm infants

Protocol summary

Summary

This study will be done with aim to assessing the effectiveness of abdominal massage and non-nutritive sucking on clinical outcomes in preterm infants. This study is a single blind clinical trial. Study population will be included all of premature infants admitted to the NICU of Imam Reza Hospital in Kermanshah. 42 patients will selected in available method and considering the number of hospitalized cases and numbers table, randomly will placed in two Intervention groups and one control group. In the intervention group, after the hand was warm and soaked in olive oil over a period of 5 days and 2 times every day at 9 am and 21 pm for 15 minutes massage will performed before feeding. During the massage supine position with the angle of 30-45 degrees head of bed are respected and according to the Vaymala techniques, abdominal massage in(I LoveYou) method will be done. second intervention group will receive non-nutritive sucking by pacifier during the 5 days and 2 times a day at 9 am and 21 pm, that 5 minutes before feeding begins and continues for 10 minutes. The control group will receive routine care. In all three groups, respiratory rate, heart rate and oxygen saturation percentage by Pulse Oximetry pre- and post-intervention, gastric residual volume and frequency of stools will be recorded. Inclusion criteria: No intestinal obstruction and abdominal. Surgery exclusion criteria: Hemodynamic instability, sepsis, severe congenital malformation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410275168N9**

Registration date: **2016-06-18, 1395/03/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-18, 1395/03/29

Registrant information

Name

Maliheh Assadollahi

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-06-14, 1395/03/25

Expected recruitment end date

2016-08-15, 1395/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of effectiveness and non effectiveness of abdominal massage and non-nutritive sucking on clinical outcomes in preterm infants

Public title

Study the effectiveness of abdominal massage and non-nutritive sucking on clinical outcomes in preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Parental consent; Infants with gestational age between (32-28); Weighing between 1750-1000 g; No bowel obstruction and abdominal surgery .Exclusion criteria: The central nervous system Diseases; Severe congenital abnormalities such as severe heart abnormalities and abdominal and intestinal disorders; Sepsis; Hemodynamic instability; Parents opting out of participation in the study; Catching necrotizing enterocolitis; A congenital anomaly abdomen and abdominal surgery; Wound and oral anomalies.

Age

From **7 months** old to **8 months** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomly based on random numbers table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Vice Chancellor for Research, Tabriz University of Medical Sciences, Street of Golgasht

City

Tabriz

Postal code

Approval date

2016-05-23, 1395/03/03

Ethics committee reference number

IR.TBZMED.REC.1395.158

Health conditions studied

1

Description of health condition studied

preterm infant

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

Respiratory rate

Timepoint

The beginning of the study, the first day of initiation of breast feeding twice a day over five days

Method of measurement

Counting the abdominal breathing by facilitator

2

Description

Heart rate

Timepoint

The beginning of the study, the first day of initiation of breast feeding twice a day over five days

Method of measurement

By Pulse Oximetry

3

Description

Oxygen saturation percentage

Timepoint

The beginning of the study, the first day of initiation of breast feeding twice a day over five days

Method of measurement

By Pulse Oximetry

4

Description

Gastric residual volume

Timepoint

The beginning of the study, the first day of initiation of breast feeding twice a day over five days

Method of measurement

By aspiration with syringe

5

Description

The frequency of stools

Timepoint

Baseline, every day for five days

Method of measurement

Observe by facilitator

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, after the hand was warm and soaked in olive oil over a period of 5 days and 2 times every day at 9 am and 21 pm for 15 minutes massage will performed before feeding. During the massage supine position with the angle of 30-45 degrees head of bed are respected and according to the Vaymala techniques, abdominal massage in(I LoveYou) method will be done.

Category

Behavior

2

Description

écond intervention group will receive non-nutritive sucking by pacifier during the 5 days and 2 times a day at 9 am and 21 pm, that 5 minutes before feeding begins and continues for 10 minutes and in total will take 15 minutes.

Category

Behavior

3

Description

The control group will receive routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Sharareh Kiani

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mehdi Farhoudi

Street address

Vice Chancellor for Research, Tabriz University of Medical Sciences, Street of Goltasht

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Sharareh Kiani

Position

Student of Ms, Emergency care of infant

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mallihe Assadollahi

Position

Ms.c of Nursing

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Sharareh Kiani

Position

Student of Ms. Nursing of Emergency care of infant

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty